

REMARKS/ARGUMENTS

Claims 75 and 77-92 are pending. By way of the present amendment, eight (8) claims have been amended and eight (8) claims has been canceled. Applicant respectfully submits that no new matter has been added by way of this amendment.

Claim	Illustrative support in the specification can be found at least at:
75	Page 35, lines 5-20 and Examples I-IV and VI.
77	Page 35, lines 5-20, page 44, line 10 to page 47, line 21.
84	Page 28, lines 18-27 and Examples I-IV.
85	Page 28, lines 18-27 and Examples I-IV.
86	Page 37, lines 21-29.
87	Page 37, lines 21-29.
88	Page 42, line 11.
89	Page 38, lines 14-27.
91	Page 35, lines 11-13; originally filed claim 13 (page 93, lines 25-27).

I. SPECIFICATION

The Office Action dated August 21, 2009 objected to the amendment filed June 11, 2007 as introducing new matter to the disclosure – “[t]he added material which is not supported by the original disclosure is as follows: The range of ‘about 0.75 mEq (mmole) to about [sic] [1.5] mEq (mmol) per 2 mg of omeprazole.’” See Office Action, at 2. Applicant respectfully submits that support for the range can be found at least in U.S. patent application. no. 09/183,422 on page 22, lines 10-13. The instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346, which is a continuation-in-part of application. no. 09/183,422, filed on October 30, 1998. Therefore, Applicant submits that the amendment filed June 11, 2007 does not constitute new matter and requests withdrawal of the objection.

II. THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN.

The Office Action rejected claims 75-82 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph, and solely to expedite the prosecution of the present application, Applicant has amended and canceled a number of claims, as indicated above, without prejudice. With regards to the “wt-%” limitations

identified on page 3 of the Office Action, Applicant has amended the claims to use alternate language but disagrees that the skilled artisan would not understand that Dr. Phillips was in possession of the invention as claimed in Applicant's previous response. Regarding the limitation "about 7 mEq to about 25 mEq," Applicant has amended the dependency of claim 88 to refer to claim 84, which recites 20 mg of omeprazole. Applicant has also amended claim 91 to recite the language found *verbatim* on page 93, lines 25-27 of the specification as originally filed in U.S. application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346. While Applicant disagrees with the suggestion that use of the term "about" versus "approximately" results in a difference in scope, in the interest of expediting prosecution Applicant made the change to "approximately."

Therefore, in view of the present amendments and foregoing remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, and should be withdrawn.

III. THE REJECTION UNDER 35 U.S.C. § 102/103 SHOULD BE WITHDRAWN.

The Office Action rejected claims 75, 77-86 and 88-92 under 102(b) based on U.S. Patent No. 6,489,346 ("Phillips"). In particular, the office action states that "the Applicant has filed preliminary amendments containing new matter with respect to the Specification and claims, the Applicant is only entitled to the filing date of the present Application of March 8, 2004." *See* Office Action, at 6. As discussed above, Applicant submits that no new matter has been introduced by way of any previously filed preliminary amendments. Therefore, U.S. Patent No. 6,489,346 is not available as a 102(b) reference, since the instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346. Applicant respectfully requests that the rejection under 102(b) be withdrawn in light of the current amendments and remarks.

IV. THE REJECTION UNDER 35 U.S.C. § 102/103 SHOULD BE WITHDRAWN.

Claims 75 and 77-92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 584,588 ("Nomura") in view of Carroll or US 5,447,918 ("McCullough") each in view of US

5,703,097 (“Kim”), US 6,268,385 (“Whittle”) and the acknowledged prior art.¹ Applicant respectfully traverses this rejection. As will be discussed below, no combination of the references cited disclosed every feature of the pending amended claims. Further, there is no motivation to combine the references in the manner suggest by the examiner nor a reasonable expectation of success thereof.

The references cited in the Office Action dated August 21, 2009, alone or in combination, fail to teach all limitations of the claims as presently amended. The cited portion of McCullough (Columns 15-16, example 12), does not disclose the claimed range of omeprazole in conjunction with the claimed range of sodium bicarbonate. Nor does Kim teach or disclose the claimed range of omeprazole and sodium bicarbonate. As the office action dated August 21, 2009 states, Whittle discloses esomeprazole, not omeprazole.

Nomura teaches an anti-ulcer composition comprising an imidazole derivative and a basic material. Nomura teaches that the total basic material to anti-ulcer compound weight ratio must be less than 20:1, preferably between about 1.1:1 and 10:1, even more preferably between about 2.1:1 and 5:1. Nomura at 6:17-21. The basic material is 50 to 2000 weight parts per 100 weight part of the imidazole derivative. Nomura at 2:41-3:36. In contrast, the pending composition comprises a buffer to omeprazole ratio of greater than 20:1 (w/w). Thus, if motivated at all from Nomura’s disclosure, the skilled artisan at the time of the invention would only have been motivated to make a composition with a total buffering agent to total active agent weight ratio of less than 20:1, not greater than 20:1 as presently claimed. Indeed, Nomura admonishes that “[i]f the amount of the basic material is too large, the administration of the composition is disturbed.” *Id.*, at 6:17-21. Based on this admonishment, a skilled artisan would not be motivated to combine the references nor have a reasonable expectation of success in the suggested combination. Rather, Nomura teaches away from such larger quantities of buffer.

¹ Applicant respectfully submits that the rejections made in any office actions in the present application are interpreted as being limited to those references specifically identified in each office action. Applicant reserves the right to further traverse, amend, supplement or otherwise respond to rejections to the extent they are based on references not expressly named. Furthermore, Applicant reserves the right to claim a priority date at least as early as January 4, 1996.

Based on the foregoing reasons and amendments, a *prima facie* case of obviousness has not been established. Accordingly, amended claims 75 and 77-92 are not obvious over the cited references. Therefore, Applicant respectfully requests withdrawal of this rejection.

V. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 75 and 77-92 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 162-196 of copending Application No. 10/407,522. In addition, Claims 75 and 77-92 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,780,882. Applicant will submit a terminal disclaimer once allowable subject matter is indicated.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the claims as submitted by way of this amendment are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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